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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,069	09/24/2004	Anne Simone Josephine Lesage	JAB-1703	3249

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,069	LESAGE ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 9/24/04 contains minor informalities, such as the class and subclass is not listed for the patents to be considered.

Claim Objections

1. Claim 9 is objected to because of the following informalities: The claim recites "mamals" which spelled incorrectly. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to how much constitutes a therapeutically effective amount or how much is necessary to provide an effective radioactive composition.

3. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what is the method of use for the radiolabeled compound or composition. It is impossible for one to use the radiolabeled compound or composition since the method is not defined.

4. Claim 11 recites the limitation "the diagnostic method". There is insufficient antecedent basis for this limitation in the claim. There is no mention of a diagnostic method in the independent claim 1 to which claim 11 depends.

5. Claim 12 recites the limitation "the marking". There is insufficient antecedent basis for this limitation in the claim. There is no mention of a marking in the independent claim 1 to which claim 12 depends.

6. Claim 13 recites the limitation "the diagnostic method". There is insufficient antecedent basis for this limitation in the claim. Again, there is no mention of a diagnostic method in the independent claim 1 to which claim 13 depends.

7. Claim 14 recites the limitation "the biological material". There is insufficient antecedent basis for this limitation in the claim. There is no mention of biological material in the independent claim 1 to which claim 14 depends.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 16 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claim 16 is directed to the use of radiolabeled compound or composition and does not provide the method of use of such compounds.

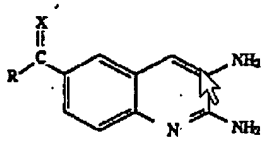
Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 1,4-6,9-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Freyne et al. (US 5,541,325).

11. Freyne et al. (US 5,541,325) teaches of the stereochemically isomeric forms of quinoline intermediate compounds (below) (column 5, line 5; abstract).



12. The quinoline intermediate compounds where R is hydrogen, phenyl (substituted) and >C=X is >C=O, >C=N-O-R^1 or >C-CH-R^2 (column 1, lines 41-52; column 3, lines 29-34). The compounds of the disclosure encompass those of the instant claims, such as the instant claims may have R^1 as aryl, R^2 and R^3 as amino and X as O, or N-R^7 with R^7 as hydroxy. In regards to the radioactive atom, the disclosed quinoline and quinolinone compounds would inherently contain at least one radioactive atom substituted at one position of the quinoline and quinolinone compounds due to the natural abundance of ^3H. The instant claims 1,4-6 are directed to radiolabeled quinoline

and quinolinone compounds. The intended use of the compounds, such as the steps of administration to mammals and detecting emissions from the compounds is not given any patentable weight since the instant claims 9-15 and 17 are drawn to the compounds and not to the methods of using such compounds. Since the teachings of Freyne et al. (US 5,541,325) anticipates the claimed composition, the property of such a claimed composition will also be anticipated by the prior art teachings, since the properties, namely marking or identifying a mGlu1 receptor in biological material, are inseparable from its composition. Therefore, if the prior art teaches the composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

13. Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Mabire et al. (WO02/28837A1).

14. Mabire et al. (WO02/28837A1) teaches of the pure steroisomeric forms of the quinoline and quinolinone derivatives and their use in medicine (p1, lines 4-6; p2-5; p25,

line 10). The quinoline and quinolinone derivatives show mGluR1 antagonistic activity and in the treatment or prevention of glutamate-induced diseases by administering the compounds to mammals (p26, lines 2 and 7-29). The compounds of the disclosure encompass those of the instant claims, such as the R^1-C(=X) moiety may be linked to another position than the 7 or 8 position, thus anticipating position 6 (p5, line 1). In regards to the radioactive atom, the disclosed quinoline and quinolinone compounds would inherently contain at least one radioactive atom substituted at one position of the quinoline and quinolinone compounds due to the natural abundance of ^3H. The radiolabeled R214127 compound of the instant claims is anticipated by the disclosed compounds (p97, see 432). The instant claims 1-15 and 17 are directed to radiolabeled quinoline and quinolinone compounds. The intended use of the compounds, such as the steps of administration to mammals and detecting emissions from the compounds is not given any patentable weight since the instant claims 9-15 and 17 are drawn to the compounds and not to the methods of using such compounds. Since the teachings of Mabire et al. (WO02/28837A1) anticipates the claimed composition, the property of such a claimed composition will also be anticipated by the prior art teachings, since the properties, namely marking or identifying a mGlu1 receptor in biological material, are inseparable from its composition. Therefore, if the prior art teaches the composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

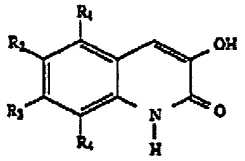
Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai et al. (US 5,597,922) in view of Freyne et al. (US 5,541,325)

17. Cai et al. (US 5,597,922) discloses the radiolabeled quinolinone compounds (below) (column 5, lines 60+).



18. These quinolinone compounds are antagonists at the glycine binding site found on the NMDA receptor, which is a glutamate receptor (column 4; column 1, lines 20-24). The in vitro characterization/determination of the glycine binding site on the glutamate receptor involves isotopically labeling such quinolinone compounds with a ^{3}H, ^{11}C, ^{18}F, etc. at one or more atoms of the compounds (column 57, lines 33-39). Pharmaceutically acceptable aqueous formulation of the compounds may be administered to any animal for such determinations (column 55, lines 51-65; column 57, lines 19-21). Cai et al. (US 5,597,922) does not disclose the same phenyl substituents R_{1-4} as those of the instant claims.

19. Freyne et al. (US 5,541,325) discloses the stereochemically isomeric forms of quinoline intermediate compounds as well as that listed above. The phenyl substituents of Freyne et al. encompass those of the instant claims and are substituted at the C-6 position of the phenyl ring.

20. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize different substituents, such as those disclosed by Freyne et al. (US 5,541,325), on the phenyl ring of the radiolabeled compounds of Cai et al. (US 5,597,922) to provide for more selective drug ligands to bind to the desired binding site, i.e. glutamate receptor such as NMDA. The combined disclosures generate radiolabeled compounds that provide for easier determination/characterization of the binding site of a subject, organ, tissue, etc. via well-known detection/imaging techniques, such as PET.

21. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai et al. (US 5,597,922) in view of Mabire et al. (WO02/28837A1).

22. Cai et al. (US 5,597,922) discloses the radiolabeled quinolinone compounds as well as that listed above. Cai et al. (US 5,597,922) does not disclose the same phenyl substituents R_{1-4} as those of the instant claims.

23. Mabire et al. (WO02/28837A1) discloses pure steroisomeric forms of the quinoline and quinolinone derivatives and their use in medicine as well as that listed above.

24. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize different substituents, such as those disclosed by Mabire et al. (WO02/28837A1), on the phenyl ring of the radiolabeled compounds of Cai et al. (US 5,597,922) to provide for more selective drug ligands to bind to the desired binding site, i.e. glutamate receptor such as NMDA. The quinoline and quinolinone derivatives of Mabire et al. are disclosed to show mGluR1 antagonistic activity. Therefore, it would be obvious that the combined disclosures generate radiolabeled compounds that bind the mGluR1 receptor and would provide an easier determination/characterization of the mGluR1 receptor site of a subject, organ, tissue, etc. via well-known detection/imaging techniques, such as PET.

Double Patenting

25. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

26. Claims 1-6,9-15 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4,8,9,11,15,18 and 19 of copending Application No. 11/133,678. Although the conflicting claims are not identical, they are not patentably distinct from each other because quinoline and quinolinone compounds of copending Application No. 11/133,678 encompass those of the instant claims. The R^2 substituent is not defined in all of the claims of the copending Application No. 11/133,678 and therefore would encompass those substituents of the instant claims. The instant claims discloses the composition of compounds and a pharmaceutically acceptable carrier which may be administered to mammal, thus the generation of such as composition is anticipated by the instant claims. The method of antagonizing a glutamate receptor with the antagonist quinoline and quinolinone compounds of the instant claims involves determining the binding to the mGlu1 receptor upon administration to biological material, such as tissues of a warm-blooded animal. In regards to the radioactive atom, the disclosed quinoline and quinolinone compounds would inherently contain at least one radioactive atom, such as ^3H substituted at one position of the quinoline and quinolinone compounds due to the natural abundance of ^3H.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
December 26, 2006

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER